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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,921	03/27/2001	Ronald C. Lundquist	950.005US7	4952

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/818,921

LUNDQUIST ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The amendment to the claims and the cancellation of claim 1 have been entered, as requested in Paper no. 10, filed 21 March 2003. Claims 10-32 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant urges that the crossed out references in the IDS on pg 6-9 and elsewhere because the rules provide for submission of a list of other information for consideration; thus, the information must be considered by the examiner even if it is not suitable for publication on the face of the file (response pg 4-5).

This is not found persuasive. MPEP §609 states that an information disclosure statement be must follow the requirements of 37 CFR 1.97 and 37 CFR 1.98, and that these require that “Each publication must be identified by publisher, author (if any), title, relevant pages of the publication, and date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.” Furthermore, only the English portion of a non-English document must be considered; in the instant IDS, documents that were solely in an language other than English were not considered.

The foreign patent documents on pg 3 of the IDS have been considered, and a copy of that page is being sent with this action. The crossed out document is a duplicate of the reference immediately above it.

Response to Arguments

4. The rejection of claims 10-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,331,665 is withdrawn in light of Applicant's arguments.

Claim Rejections - 35 USC § 103

5. Claims 10-24, 26-27 and 29-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tomes et al (US Patent 5,886,244, filed June 1988) in view of each of Barton et al (1987, Plant Physiol. 85:1103-1109), Vaeck et al (1987, Nature 328:33-37) and Adang et al (1985, EP 142,924). The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 October 2002. Applicant's arguments filed 31 March 2003 have been fully considered but they are not persuasive.

Applicant urges that the references fail to teach all the elements of the claims. Applicant cites *Adang v. Fischhoff* in which an Adang patent was found to be non-enabled for expression of a full-length Bt toxin in tobacco and thus in the non-exemplified plant tomato. Applicant urges that in the instant case no examples of insect resistant maize plants expressing Bt genes have been cited; Adang, Barton and Vaeck only teach tobacco plants transformed with truncated Bt. Applicant urges that *Adang* states that success in tobacco does not provide enablement in another dicot, much less a monocot like maize (response pg 5-7).

This is not found persuasive because *Adang v. Fischhof* only finds non-enablement for expression of full-length toxin. *Adang* states that Barton et al and Vaeck et al teach successful

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expression of a truncated protein in plants (62 USPQ2d 1504 (CA FC 2000) pg 1512 and 1508).

The issue of whether the plants were resistant because they produced full-length toxin is irrelevant to this rejection; the claims of the instant invention are not drawn to expression of a full-length toxin.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant urges that Tomes et al does not provide fertile transgenic maize plants, and submit the reference is not enabling for production of transgenic maize, let alone a transgenic maize expressing a modified Bt. Applicant urges that even if it is assumed that Tomes et al teach a method of transforming maize, the mere citation of a general transformation method neither enables production of insect resistant maize or reasonable success under 35 USC 103 (response pg 7-8).

This is not found persuasive because Tomes et al do teach fertile transgenic maize plants in claims 1-11. Claims in an issued patent are assumed to be enabled unless shown otherwise in the appropriate proceedings. As to arguments that the mere citation of a general transformation method neither enables production of insect resistant maize or reasonable success under 35 USC 103, Applicant is arguing against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*,

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800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is not clear what about expression of genes in maize is unpredictable.

6. Claim 25 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Tomes et al (US Patent 5,886,244, filed June 1988) in view of each of Barton et al (1987, Plant Physiol. 85:1103-1109), Vaeck et al (1987, Nature 328:33-37) and Adang et al (1985, EP 142,924), as applied to claims 10-24, 26-27 and 29-32 above, and further in view of Adang et al (US Patent 530,831, filed September 1988). The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 October 2002. Applicant's arguments filed 31 March 2003 have been fully considered but they are not persuasive.

Applicant urges that because the rejection has not been applied to parent claim 10, and there is not indication that the instant rejection adds anything with respect to the rejection of claim 10, the instant claim is not obvious over the cited references (response pg 8).

This is not found persuasive. The rejection is made over claim 10 (see the underlined words two paragraphs above). As claim 10 is a parent claim, the teachings of Adang et al (1988) apply to it as well as to claim 25.

7. Claims 10-15, 18-24, 27, 29 and 31-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over each of Klein et al; (1989, Plant Physiol. 91:440-444), Klein et al (1988a, Proc. Natl. Acad. Sci USA 85:4305-4309), Klein et al (1988b, Bio/technol. 6:559-563) and Sanford et al (US Patent 5,036,006, filed June, 1986) in view of Shillito et al (US Patent 5,350,689, filed November, 1988). The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 October 2002. Applicant's arguments filed 21 March 2003 have been fully considered but they are not persuasive.

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Applicant urges that none of the references provide the necessary expectation of success, nor are all the elements of the claims provided by an enabling method for maize transformation. Applicant urges that none of the Klein references teach a method for creation of fertile transgenic maize plants; they only teach transformation of maize cells (response pg 8-9).

This is not found persuasive. The Klein references teach transformation of the cells by particle bombardment; Shilito et al teaches regeneration into plants of maize cells transformed with Bt endotoxin genes.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant urges that the portion of Shillito described as teaching production of progeny from regenerated transformed maize plants is prophetic and submit that Shillito is not enabling (response pg 9).

This is not found persuasive because Shillito et al do teach fertile transgenic maize plants in claims 1-20 (see the last line in parts (d) of claims 1 and 11, the second line in part (j) of claim 1, and the second line in part (k) of claim 11. Claims in an issued patent are assumed to be enabled unless shown otherwise in the appropriate proceedings.

Applicant urges that no basis is given for the assertion that vectors comprising the N-terminal 50% of the Bt toxin would be more efficiently expressed in maize. (response pg 9).

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This is not found persuasive because Shillito teach expression of truncated genes in maize plants (examples 22-24). The instant claims are not drawn to more efficient expression, and thus Applicant is arguing a limitation not found in the claims.

Double Patenting

8. Claims 10, 14-15, 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,484,956 in view of Adang et al (US 5,380,831, filed September, 1988). The rejection is repeated for the reasons of record as set forth in the Office action mailed 21 October 2002, as applied to claims 10-15 and 18-32. Applicant's arguments filed 31 March 2003 have been fully considered but they are not persuasive.

Applicant urges that only the claims portion of an issued patent may be used in this rejection (response pg 11).

This is not found persuasive because the claims of the issued patent are drawn to plants that would be produced by the method of the instant application. The claims of the issued patent are drawn to plants transformed with a preselected DBA sequence encoding a Bt endotoxin, wherein the DNA is introduced by microprojectile bombardment. One would have to use the method claimed in the instant application to produce those plants. The rejection has been withdrawn for claims 11-13, 18 and 20-32.

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Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
June 12, 2003



AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
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